

REMARKS

Examiner's Rejections and Objections

The foregoing Amendment and remarks which follow are responsive to the initial Office Action mailed March 4, 2004. In that Office Action, the Examiner first required Applicant to affirm its provisional election to prosecute the invention of extraction with water. Applicant affirms such election and thus cancels Claims 3-12 from current prosecution.

Further in that Office Action, the Examiner rejected Claims 1, 2 and 13-16 under 35 U.S.C. 102(b) as being anticipated by the JP 402258725 reference ("the '725 reference"). The Examiner also rejected Claims 1 and 13-16 under 35 U.S.C. §102(b) as being anticipated by the CN 1200281 or the JP 409249578 reference ("the '281 or '578 reference," respectively).

Furthermore, Claims 1, 2 and 13-16 were rejected under 35 U.S.C. §102(b) as being anticipated by the US 20010046524 reference ("the '524 reference"). Lastly, the Examiner additionally rejected Claims 1, 2 and 13-16 under 35 U.S.C. §103(a) as being unpatentable over the '281 or '578 reference taken with the '725 or '524 reference.

However, as will be demonstrated below, Applicant respectfully submits that the present invention is novel and unobvious over those references.

Amended Independent Claim 1

Applicant has amended independent Claim 1 to emphasize certain subject matter which is believed to be allowable over the above-identified prior art references. More specifically, Applicant has clarified independent Claim 1 to recite a pharmaceutical composition which comprises "an extract of Cortex Eucommiae for activating alkaline phosphatase in osteoblast cells of a living being to induce differentiation and mineralization of the osteoblast cells to thereby promote regeneration of hard tissue."

Essentially, the present invention is a pharmaceutical composition which contains Cortex Eucommiae extract as its ingredient. The Cortex Eucommiae extract in the pharmaceutical composition is effective to active alkaline phosphatase activities in the osteoblast cells of a living being such as a human. Such activation of alkaline phosphatase activities in the osteoblast cells induces differentiation and mineralization of the cells. Hence, the present composition containing the Cortex Eucommiae may be optimally used as a pharmaceutical agent to promote regeneration of hard tissues. This is very useful in the prevention and treatment of hard tissue disorders such as osteoporosis and periodontal disease accompanied by alveolar bone destruction.

Applicant respectfully submits that all the prior art references cited by the Examiner for amended base Claim 1 do not individually or collectively teach or suggest such unique feature. It would be novel, and further unobvious to one of ordinary skill in the art, to develop a pharmaceutical composition which comprises Cortex Eucommiae extract to activate alkaline phosphatase in osteoblast cells to induce differentiation and mineralization of those cells to thereby promote regeneration of hard tissues.

With respect to the '725 reference which allegedly anticipates the present invention, Applicant submits that the '725 reference fails to disclose a pharmaceutical composition comprising Cortex Eucommiae extract for activating alkaline phosphatase in osteoblast cells to induce differentiation and mineralization of such cells to promote regeneration of hard tissues.¹ In fact, the '725 reference is not understood to

¹ As the Examiner is aware, anticipation cannot be established unless a single prior art reference discloses each and every element of the claimed invention. Structural Rubber Co. v. Park Rubber Co., 749 F.2d 707, 223 U.S.P.Q. 1264 (Fed. Cir. 1984). Further, for anticipation to apply, all of the claimed elements must be found in exactly the same situation and united in the same way to perform the identical function in a single unit of the prior art. (See, e.g., Studiengesellschaft Kohle m.b.H. v. Dart Industries, 762 F.2d 724, 726, 220 U.S.P.Q. 841, 842 (Fed. Cir. 1984)). Even further, any inherency which is applied in the context of anticipation "does not

disclose a pharmaceutical composition or the use thereof in regards to activating alkaline phosphatase in osteoblast cells, or for inducing differentiation and mineralization of those cells, or for promoting regeneration of hard tissues. Rather, the '725 reference is directed toward "a remedy for preventing and treating pseudorabies containing specific crude drugs as active ingredients without causing any problems in formation of strongly toxic viruses and residual vaccine, etc., in animal bodies caused by administration of the vaccine." (See, Page 1, paragraph 7). This is clearly different and distinguishable from the features of the present invention which are well emphasized above. In this respect, Applicant respectfully submits that the '725 reference fails to anticipate the pharmaceutical composition of the present invention which is now emphasized in amended independent Claim 1.

The '281 reference also fails to disclose the present invention in a proper anticipatory manner. More specifically, the '281 reference does not teach or suggest a pharmaceutical composition or the use thereof directed to activating alkaline

embrace probabilities or possibilities." Trintec Industries Inc. v. Top-U.S.A. Corp., 63 U.S.P.Q.2d 1597, 1601 (Fed. Cir. 2002) (holding of no express or inherent anticipation in a scenario where a catalog taught printing methods but not "creating" anything in a computer as the latter was not disclosed therein).

phosphatase in osteoblast cells, or to inducing differentiation and mineralization of those cells, or to promoting regeneration of hard tissues. On the contrary, the '281 reference is directed toward a "health care liquor . . . which are soaked in grain spirit." (See, Page 1, paragraph 10). This is understood to be the extent of its disclosure, and the '281 reference fails to expressly or impliedly indicate the specific pharmaceutical composition of the present invention which is recited in amended independent Claim 1.

Moreover, the '578 reference further fails to teach or suggest the present pharmaceutical composition or the use thereof which activates alkaline phosphatase in osteoblast cells, or which induces differentiation and mineralization of osteoblast cells, or which promotes regeneration of hard tissues. Rather, the '578 reference describes "a crude drug extract . . . useful as an antileukopathic or an antipoliotic therapeutic agent." (See, Page 1, paragraph 7). It should be further pointed out herein that such crude drug extract is "obtained with a 50% ethanol." (See, Page 2, paragraph 8). As such, it is respectfully submitted that the '578 reference fails to anticipate the pharmaceutical composition that is specified in amended independent Claim 1.

In addition, the '524 reference does not teach or suggest a pharmaceutical composition comprising Cortex Eucommiae extract

for activating alkaline phosphatase in osteoblast cells to induce differentiation and mineralization of such cells to promote regeneration of hard tissues. As understood, the '524 reference is directed to "a method for modulating steroidogenic activity and a composition useful for same." (See, Page 1, paragraph 1). As understood, the '524 reference is essentially geared toward "extracting active steroidogenic compounds from EU plants." It is not believed to disclose and thus anticipate the pharmaceutical composition of the present invention which activates alkaline phosphatase in osteoblast cells, or which induces differentiation and mineralization of osteoblast cells, or which promotes regeneration of hard tissues.

With respect to the combination of the prior art references noted above which allegedly renders the present invention obvious, Applicant respectfully submits that any selective combinations of those prior art references also fail to disclose the pharmaceutical composition of the present invention, or the use thereof, which activates alkaline phosphatase in osteoblast cells, or which induces differentiation and mineralization of osteoblast cells, or which promotes regeneration of hard tissues. Based upon Applicant's close review of all the prior art references at hand which are amply discussed above, Applicant believes that none of the references discloses or even suggests the features of the present pharmaceutical composition

which are emphasized above and expressly claimed in amended independent Claim 1. Thus, Applicant respectfully submits that the '725, '281, '578 and '524 references individually or collectively fail to obviate the present composition's features that are now emphasized and expressly claimed in amended independent Claim 1.

Applicant respectfully submits that amended base Claim 1 is novel and unobvious in view of the cited prior art references, and thus allowable. Insofar as the amended independent Claim 1 is believed to be allowable, its respective dependent claims are also believed to be allowable as they are further limitations of their independent claim.

For the foregoing reasons, Applicant respectfully requests reconsideration of the rejections under 35 U.S.C. §§ 102(b) and 103(a).

Request for Allowance

On the basis of the foregoing, Applicant respectfully submits that all the stated grounds of rejections have been overcome, and that all the claims which are now pending in this case are in condition for allowance. An early Notice of Allowance is therefore respectfully requested.

Should the Examiner have any suggestions for expediting allowance of the application, the Examiner is invited to contact Applicant's representative at the telephone number listed below.

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